REMARKS

Claims 5-7, 9-12, and 14-23 are pending. Applicants gratefully acknowledge the Office's withdrawal of its previous rejections of claim 10 under 35 U.S.C. § 103(a) and claim 19 under 35 U.S.C. § 102(b).

The Office maintains its rejection of claims 5, 6, 11, 12, 17, 18, 20, and 23 under 35 U.S.C. § 102(b) and its rejection of claims 6, 7, 11, and 17-21 for alleged obvious-type double patenting. Claims 9, 11, 15, 16, 20, and 21 are newly objected to under 37 C.F.R. § 1.75(c) and claims 21 and 23 are newly objected to under 37 C.F.R. § 1.75. The Office also newly rejects claims 10 and 22 under 35 U.S.C. § 112, first paragraph; claims 10, 12, and 22 under 35 U.S.C. § 112, second paragraph; claims 17, 18, and 20-22 under 35 U.S.C. § 102(b); and claims 5-7, 10-12, and 17-23 under 35 U.S.C. § 103(a). Applicants address each outstanding rejection under its respective statutory section below.

Objections to Claims

The Office objects to claims 9, 11, 15, 16, 20, and 21 under 37 C.F.R. § 1.75(c) because they are allegedly in improper dependent form for not further limiting the subject matter of a previous claim. According to the Office, claim 11 does not further limit claim 6 because claim 11 does not contain an additional embodiment to further limit claim 6. The Office believes that the recitation of a "diagnostic aid" does not constitute a specific embodiment. Solely to facilitate prosecution, Applicants have amended claim 11 into independent form. This amendment does not alter the scope of claim 11, but renders the Office's objection moot.

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The Office also believes that claims 20 and 21 do not further limit claim 17 for two reasons. First, claim 17 recites an "antibody" while claims 20 and 21 recite "antibodies." Thus, according to the Office, the scope of claims 20 and 21 is broader than the scope of claim 17. Regarding this specific point, Applicants contend that the scope of claims 20 and 21 is not broader than the scope of claim 17. Claim 17 does not cover just one antibody. Rather, there are many antibodies that may classify as an "anti-erythropoietin (EPO) antibody directed against epitopes that bind to the EPO receptor." Claims 20 and 21 simply refer to that population of antibodies. The Office's second reason for this objection is that the recitation of a "diagnostic aid" and "pharmaceutical composition" allegedly does not further limit claim 17. Applicants note that the same objection may be applied to claims 15 and 16 as they relate to claim 9. To facilitate prosecution, Applicants have amended claims 16 and 20 into independent form and claim 21 to recite an excipient. As the Office's objection is now rendered moot, Applicants request that this objection be withdrawn.

The Office also notes that claim 9 recites an anti-idiotype antibody, which, according to the Office, is not further limiting of claim 6. Applicants have amended claim 9 into independent form without changing its scope. This objection is also rendered moot.

Claim 21 is objected to as allegedly a substantial duplicate of claim 20 and having identical scope. As amended, claim 21 also recites a "pharmaceutically acceptable excipient," which is not necessarily present in the diagnostic aid of claim 20. In addition, a diagnostic aid and a pharmaceutical composition are two distinct

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preparations as the latter is designed for use in animals or humans and would require a higher standard of preparation than a diagnostic aid that would presumably be used *in vitro* to detect the presence of EPO. Thus, Applicants contend that claims 20 and 21 do not share the same scope and request that the Office withdraw its objection.

The Office similarly objects to claim 23 as an alleged duplicate of claim 6. The Office believes that claim 23 recites the antibody of claim 6, which is directed at epitopes which bind to the EPO receptor. Applicants respectfully contend that, in making this objection, the Office is construing the scope of claim 6 too narrowly. Specifically, claim 6 recites an EPO-neutralizing antibody that is directed to the P2 peptide or the P2/1 peptide. As Applicants have discussed in a prior response, an antibody may neutralize EPO activity in a variety of ways. Those means include creating an allosteric change in the protein, binding near (but not on) the receptor binding site to physically occlude the receptor binding site, or by binding the EPO receptor binding site directly. Claim 23 further defines the neutralizing antibody by requiring that it bind to epitopes that bind the EPO receptor. Furthermore, there may be several epitopes present in P2 and P2/1 not all of which bind the EPO receptor.

Finally, claim 14 is objected to as being dependent on a rejected base claim. To facilitate prosecution, Applicants have amended claim 14 to incorporate the features of claim 6. As this amendment merely converts claim 14 to independent form, its scope has not been altered. Applicants request that the Office's objections to the claims as discussed above be withdrawn in light of the amendments and arguments above.

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Rejections Under 35 U.S.C. § 112

The Office rejects claims 10, 12, and 22 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Office believes that claim 12 lacks antecedent basis in claim 5, that claim 10 lacks antecedent basis in claim 6, and that claim 22 lacks antecedent basis in claim 17. Specifically, claim 5 recites a method while claim 12 recites a product. Claim 10 recites a method and claim 6 recites a product. Claim 22 recites a method and clam 17 recites a product. Applicants respectfully traverse.

The Office is not applying the correct standard for looking at the relationship between these claims. For example, claim 12 refers to a peptide as defined in claim 5. Though claim 5 is a method claim, it clearly describes an EPO peptide, making the scope of claim 12 clear and definite. Likewise, claim 10 refers to an antibody as defined in claim 6 and claim 6 is a claim to an antibody again making the antecedent basis clear. Finally, claim 22 refers to an antibody as defined in claim 17 and claim 17 is a claim to an antibody. Thus, claims 6 and 17 are used to further define the methods of claims 10 and 22, respectively. Thus, this rejection should be withdrawn.

Claim 22 also stands rejected as allegedly indefinite because it is a method claim that does not list any steps. Solely to faciltate prosecution and to clarify the invention, Applicants have amended claim 22 to recite steps that describe the use of the described antibodies in a chromatographic process. Applicants request that this objection be withdrawn.

The Office rejects claims 10 and 22 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such

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a way as to indicate that the inventors had possession of the invention at the time of filing. Specifically, the Office alleges that these claims encompass isolation of EPO derivatives and argues that the specification does not teach or define derivatives. Moreover, the Office believes that the specification mentions only EPO peptides. In contrast, Applicants note that the specification discusses all three forms of EPO described in claims 10 and 22. First, as the Office acknowledges, the specification at page 3, lines 29-35 discusses EPO peptides. Second, isolation of full length EPO is taught at page 11, lines 29-33 and in Example 7 on page 16 of the specification. Third, Example 7 also describes the purification of EPO muteins by affinity chromatography. The specification also describes EPO muteins as modified EPO molecules and further instructs that antibodies to these muteins may be generated. *See* specification at p. 7, lines 2-8. This teaching coupled with the teaching in Example 6 of how to attach antibodies to a chromatography medium instructs the skilled artisan how to isolate such derivatives.

Finally, Applicants note that the Office itself has demonstrated that a skilled artisan would be able to identify additional derivatives besides the amino acid mutein described at page 7 of the specification. *See* Office Action at p. 4, lines 14-17. The Office also notes that some of the potential derivatives of EPO may not be functional. This observation is beside the point, as claims 10 and 22 do not require that the EPO be functional. For the above reasons, the specification does in fact contain teachings that indicate that the inventors were in possession of the invention of claims 10 and 22 at the time of filing. Applicants therefore request the Office's withdrawal of this rejection.

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1300 I Street, NW
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Rejections Under 35 U.S.C. § 102

Claims 17 and 18 remain rejected under § 102(b) as allegedly anticipated by Sytkowski et al. (*J. Biol. Chem.* 262:1161-65 (1987); "Sytkowski"). Applicants note that the Office also revisits claims 20 and 21, which were not addressed in the previous Office Action. Because claims 18, 20, and 21 as amended are either dependent on claim 17 or contain the same antibody as claim 17, Applicants traverse by discussing the Office's rejection in the context of claim 17.

First, the Office continues to assert that Sytkowski discloses two neutralizing antibodies to EPO, anti-peptide 99-118 and anti-peptide 111-129, which allegedly bind to the receptor binding domain of EPO. The Office attempts to support its conclusion by citing Table 2 and p. 1164, at line 16 of the last paragraph to line 7 of the first paragraph on p. 1165. These sections discuss the neutralizing activity of antibodies against the 99-118 and 111-129 peptides. Again, the Office has arrived at the indirect conclusion that because there is some neutralizing activity, the antibodies must be binding to the part of EPO that binds the EPO receptor ("EPOR"). As Applicants have previously indicated, there are other mechanisms, discussed in Sytkowski, that can account for Sytkowski's neutralizing activity that do not require the antibody to bind to the EPOR binding portion of EPO. Specifically, these antibodies may inhibit EPO activity by binding near the EPOR binding domain and sterically inhibiting or physically blocking the interaction of EPO with its receptor; or neutralizing antibodies may bind nowhere near the receptor domain on EPO, but many nonetheless inhibit EPO function by causing an allosteric change in the hormone molecule. Couple these alternatives with

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Sytkowski's direct admission that peptides 99-118 and 111-129 do not bind to the EPOR, and it is clear that the Office's conclusion and its evidence to support it are flawed. Applicants note that the Office has continuously cited a section of Sytkowski, purporting that the "most likely" explanation of their data is that these antibodies do bind to the portion of EPO that binds the EPOR. Sytkowski's conclusion is in direct conflict with its own data, which indicates that these peptides do not bind the EPOR. See also the discussion of Wojchowski below. In addition, the Office responds to Sytkowski's admission that there is no EPOR binding by asserting that claim 17 is "drawn to antibodies and it is not required for the isolated peptides bind to EPO." Claim 17 is drawn to antibodies that are directed to epitopes that bind the EPO receptor. Because claim 17 requires binding to the EPOR, the Office's observation regarding peptides to bind EPO is not relevant.

The Office again argues that claim 17 does not require that the peptide must elicit a biological effect. This argument is irrelevant because Sytkowski's neutralization assay does not require the peptides themselves to elicit a biological effect directly. Rather, Sytkowski added the peptides to full length EPO to determine whether the peptides could block EPO activity. None of the six peptides, including 99-118 and 111-129, blocked EPO activity thus showing that none of them bind the EPOR.

Second, the Office believes that the specification states that Sytkowski's antibodies bind to the receptor domain, citing p. 2, line 33 to p. 3, line 4 which provides: "Antibodies which were able to neutralize the biological activity of EPO are prepared by Sytkowski and Donahue only with EPO peptides which correspond to positions 99 to

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118 and 111 to 129. *The authors conclude* from this that the (single) receptor-binding domain is located in the region of amino-acid positions 99 to 129 of EPO." (Emphasis added.) The passage quoted by the Office is not an indication that Applicants believe that Sytkowski's antibodies are binding to the receptor domain. Rather, it is a description of what the authors concluded and believed to be the case. As discussed above, however, upon a thorough reading of this reference, these are not Sytkowski's conclusions.

Third, the Office argues that peptides 99-118 and 111-129 are "synthetic" peptides, both of which contain a tyrosine residue not normally present in the EPO sequence and concludes that the "result reported for direct binding to the EPO receptor was . . . not solely a peptide consisting of residues 111-129." The presence of an extra tyrosine did not affect the peptide's ability to elicit antibodies in rabbits, where these antibodies bound to native, full length EPO as shown in Table 1 of Sytkowski. Thus, if these peptides, modified only slightly in their sequence, can produce antibodies that bind EPO, there is no reason to suspect that these peptides would not interact with the EPOR in an unnatural way. Applicants noted that the antibodies do bind full length EPO in the last response and the Office responds by indicating that claim 17 is not confined to epitopes that can be reproduced by short peptides retaining the biological activity of EPO. The Office's statement is again irrelevant because, as discussed above, Sytkowski's assay does not require the peptides themselves to retain biological activity; and the claim need not have that limitation in order for Applicants to make this argument.

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Fourth, the Office asserts that an epitope to which an antibody binds may be discontinuous or linear, which is true. The Office further contends that claim 17 "can read on any antibody that [binds to an epitope that bind the EPOR] regardless of whether or not the epitope can be simulated within a linear sequence or exist only in the three dimensional structure of EPO." Whether the epitopes present in the 99-118 and 111-129 peptides are linear or discontinuous, as peptides may also fold, is not important. What is clear is that, linear or not, the epitope(s) in these peptides do not bind the EPOR.

Finally, the Office continues to rely on Philo *et al.* (*Biochemistry*, 35:1681-91 (1996); "Philo") and Narhi *et al.* ((*J. Protein Chem.*, 16:213-25 (1997); "Narhi") to provide the alleged teaching that the interaction of EPO with its receptor is complex. According to the Office, because of this complexity it "may not" be possible for a small peptide to mimic the biological function of EPO. Again, the Office is speculating and still misinterprets Sytkowski's assay. Sytkowski did not conclude that these peptides did not bind the EPOR because they could not directly stimulate the EPOR and demonstrate EPO activity. Rather, Sytkowski's assay required less of these peptides in that they tested to determine whether the peptides would compete for binding to the EPOR with full-length EPO, thereby potentially blocking the ability of full-length EPO to activate the EPOR. For this reason as well, the observation that claim 17 does not recite that the epitope have the biological activity of EPO is irrelevant.

In sum, the Office continues to misinterpret the teachings of Sytkowski and has not provided any arguments that respond to those we've asserted. Applicants therefore

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request that this rejection be withdrawn.

The Office newly rejects claims 17, 18, and 20-22 under § 102(b) as allegedly anticipated by Wojchowski et al. (*Biochimica et Biophys. Acta*. 913:170-78 (1987); "Wojchowski") as evidenced by Sytkowski. According to the Office, Wojchowski discloses a method of purifying EPO using an immunoaffinity column comprising anti-111/129 antibodies, but Wojchowski does not specifically disclose that these antibodies bind a portion of EPO that binds the EPOR. Thus, the Office invokes Sytkowski to show that Wojchowski's antibodies inherently have this feature. Applicants assert that, for the reasons above, Sytkowski's antibodies to the 111-129 peptide do not bind a portion of EPO that binds the EPOR. Thus, Wojchowski does not teach all of the elements of claims 17, 18, and 20-22 and cannot anticipate these claims.

Applicants also note that Wojchowski supports the contention that Sytkowski's conclusion that these antibodies do recognize the EPOR binding region of EPO is not well-supported. Specifically, as the Office noted, Wojchowski does not describe the anti-111/129 peptide antibodies as recognizing a part of EPO that binds the EPOR. Instead, Wojchowski simply describes the 111-129 peptide as a "hydrophilic domain" of EPO. See p. 171, left column, line 8. Applicants note that the Sytkowski manuscript was submitted to the Journal of Biological Chemistry on April 4, 1986. The Wojchowski manuscript, coauthored by the same Arthur J. Sytkowski, was originally submitted September 11, 1986 and in revised form on January 5, 1987. If Dr. Sytkowski believed his conclusion as set forth in the April 1986 paper, then why would he not indicate that this peptide binds the EPOR in a subsequent manuscript like Wojchowski? Applicants

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believe that this failure to disclose this information argues in favor of a lack of confidence in the findings of the Sytkowski reference.

Claims 5, 6, 11, 12, 17, 20, and 23 remain rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Lin (U.S. Patent 4,703, 008; "Lin"). The Office asserts this rejection against claims 18 and 21 as well. As claims 5, 6, and 17 are the independent claims, we will address this rejection in light of those claims. First, the Office continues to assert that the fact that Lin's peptides had no *in vivo* EPO activity is not evidence that the peptide 144-166 does not bind directly to the EPOR and she asserts that we are arguing a limitation that is not in the claims, that of biological activity.

On the contrary, this limitation is in claim 17: that the epitope recognized by the claimed antibody binds to the EPOR. As Applicants previously noted, Lin expressly indicates that the 144-166 peptide does not have *in vivo* activity. Moreover, the lack of *in vivo* reactivity also addresses the Office's contention that it is "reasonable to conclude" that some of Lin's antibodies would react with the 152-166 peptide, thus speaking to claim 5. This observation at the least could indicate that this peptide does not present the proper protein conformation.

The Office continues to reassert alternate explanations for why the 144-166 peptide lacks *in vivo* activity. Its first hypothesis, that the peptide may be quickly degraded *in vivo*, is at best conjecture based on general knowledge in the art. Applicants argued that the Office may not use such information. *See In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002) (holding that conclusory statements based on general knowledge or common sense cannot be used to overcome deficiencies of a reference).

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Thus, the Office's attempt to fill in this gap in reasoning is improper. The Office responds by noting that it was using "common sense" in making this rejection. Common sense is also inappropriate as a means for compensating for a reference's deficiencies. The Office's second hypothesis is based on its argument as presented in Sytkowski. Specifically, the Office believes that a conformational change may be needed in order for the 144-166 peptide to bind the EPOR, citing Philo and Nahri. For the reasons set forth above in Sytkowski, this hypothesis is without merit.

Second, the Office continues to assert that because it is reasonable to believe that antibodies to Lin's 144-166 peptide would also bind the 152-166 peptide and that antibodies that bind the 152-166 peptide are inherently neutralizing, Lin's antibodies are also inherently neutralizing. *See* current Office Action at p. 13, lines 1-7. The Office has acknowledged that Lin does not disclose that their antibodies have neutralizing activity. In our prior response, Applicants opined that the Office's argument did not meet the U.S. case law standards of inherency. Specifically, for a characteristic to be inherent, it must invariably or necessarily be present. The Office's standard of "reasonable to conclude," as discussed above, sounds more like a probability rather than a certainty.

The Office now responds by attempting to shift the burden to Applicants to show that Lin's antibodies do not anticipate claims 5, 6, and 17. Specifically, the Office has rephrased the issue to be "whether [sic] or not 'consisting essentially of a peptide less than the complete erythropoietin sequence . . . consisting of 152-166' would be inherently comprised by the 144-166 peptide of Lin." *See* current Office Action p. 11,

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lines 20-22. Indeed, this is not the issue raised by Applicants' arguments. Applicants continue to challenge the Office's assertion that antibodies to Lin's 144-166 peptide would inherently bind the 152-166 peptide and that because antibodies that bind the 152-166 peptide are inherently neutralizing, Lin's antibodies are also inherently neutralizing. This line of reason speaks especially to claim 6, which recites neutralizing activity. For the above reasons, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 17-21 are newly rejected under 35 U.S.C. § 103(a) as allegedly obvious over Sytkowski in view of Kaplan et al. (*Monoclonal Antibodies in Clinical Medicine*, 1982; "Kaplan"). Specifically, the Office contends that Sytkowski teaches the polyclonal serum of claim 17, but does not teach monoclonal antibodies ("MAbs"). Kaplan allegedly teaches the benefits of MAbs. The Office concludes that it would be obvious for the skilled artisan to make MAbs to the 111-129 peptide and that the motivation to do so lies in the general advantages of MAbs and a reasonable expectation of success. Applicants respectfully traverse.

For the reasons set forth above, Sytkowski does not teach the polyclonal serum of claim 17. Likewise, Kaplan does not teach the antibody of claim 17. Thus, neither reference alone or in combination can make the invention of claims 17-21 obvious. In addition, a general recitation of the benefits of MAbs does not make the specific production of an anti-EPO monoclonal antibody obvious. Kaplan does not provide any motivation for that specific application nor does Sytkowski. Thus, neither of these

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1300 I Street, NW
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references alone or in combination can make claims 17-21 obvious.

The Office newly rejects claims 5-7, 10-12, and 17-23 under 35 U.S.C. § 103(a) as allegedly obvious over Miyazaki et al. (*J. Immunol. Meth.* 113:261-67 (1988); "Miyazaki") in view of Lin. According to the Office, Lin teaches the embodiments of claims 5, 6, 11, 12, 17, 18, 20, 21, and 23 but does not teach a method in which the 144-166 peptide may be used to generate MAbs useful for affinity purification of EPO. Miyazaki allegedly teaches MAbs against human EPO and immunoaffinity columns comprising these MAbs. The Office concludes that it would be obvious to substitute Lin's 144-166 peptide into Miyazaki's method and that a skilled artisan would have been motivated to do so because of Miyazaki's alleged teaching on the superiority of affinity columns based on MAbs.

As discussed above, Lin does not teach the embodiments of claims 5, 6, 11, 12, 17, 18, 20, 21, and 23 as the Office believes. Likewise, Miyazaki does not teach the invention of these claims. Specifically, Miyazaki generated MAbs against human EPO and stated that they did not know what regions of EPO these MAbs bind. In addition, none of Miyazaki's MAbs neutralized the activity of EPO. Miyazaki then concludes that they do not bind the active site of EPO, i.e., the region that binds the EPOR. *See* p. 266, right column, first full paragraph. In addition, Miyazaki's immunization method employed full-length EPO, rather than an peptide consisting essentially of part of the EPO protein as recited in claim 5. Thus, because neither reference teaches the embodiments of claims 5, 6, 11, 12, 17, 18, 20, 21, and 23, they cannot make the

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202.408.4000
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invention of claims 5-7, 10-12, and 17-23 obvious. Applicants therefore respectfully request that these rejections under 35 U.S.C. § 103(a) be withdrawn.

Obvious Type Double Patenting

Claims 6, 7, 11, and 17-21 remain rejected based on obvious type double patenting in light of U.S. Patent 5,712,370. Applicants request that the Office hold this rejection in abeyance until the patentable subject matter in this application has been determined.

Conclusion

Applicants respectfully request that this Amendment be entered by the Office, placing claims 5-7, 9-12, and 14-23 in condition for allowance.

In view of the foregoing remarks, Applicants submit that their claimed invention is not anticipated in view of the prior art reference cited against this application. Applicants therefore respectfully request the entry of this Amendment, the Office's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any additional extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

By: Carol P. Einaudi

Carol P. Einaudi
Reg. No. 32,220

Date: May 20, 2003

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com